



26 November 2013  
EMA/800904/2013 Corr. 1  
Committee for Medicinal Products for Human Use (CHMP)

## Assessment report

### Tecfidera

**Common Name:** dimethyl fumarate

**Procedure No.** EMEA/H/C/002601/0000/Rev 1

### Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.



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9HPT	Nine-Hole Peg Test
AE	Adverse Event
AGIS	Acute Gastrointestinal Symptom Scale
AKr1b8	Aldo-Keto Reductase Family 1 Member B8
ALT	Alanine transaminase/Alanine Aminotransferase
ANOVA	Analysis of Variance
ARR	Annualised Relapse Rate
ASA	Acetylsalicylic Acid
AST	Aspartate transaminase/Aspartate Aminotransferase
ATP	Adenosine Triphosphate
AUC	Area Under Curve
B2M	Beta-2 Microglobulin
BCS	Biopharmaceutics Classification System
BID	Twice Daily
BUN	Blood Urea Nitrogen
CEP	Certificate of Suitability of the European Pharmacopeia
CHMP	Committee For Medicinal Products for Human Use
CI	Confidence Interval
Cl/F	Apparent Clearance
Cmax	Peak Plasma Concentration
CNS	Central Nervous System
CREA	Creatinine
CV	Cardiovascular
CYPs	Cytochromes
DMF	Dimethyl Fumarate
DMFAE	Dimethylfumaric ester
DMT	Disease Modifying Therapy
DSC	Differential Scanning Calorimetry
EAE	Experimental Autoimmune Encephalomyelitis
ECG	Electrocardiogram
EDSS	Expanded Disability Status Scale
EE	Efficacy Evaluable
eGFR	Estimated Glomerular Filtration Rate

ERA	Environmental Risk Assessment
ESRD	End Stage Renal Disease
FA	Fumaric Acid
FACT	Fumaric acid compound therapy
FT-IR	Fourier Transform Infra-Red Spectroscopy
GA	Glatiramer acetate
GC	Gas Chromatography
Gclc	Glutamate –cysteine ligase catalytic subunit
GCP	Good Clinical Practices
Gd	Gadolinium
GFSS	Global Flushing Severity Scale
GGT	Gamma Glutamyl Transferase
GI	Gastrointestinal
GLP	Good Laboratory Practices
GSH	Gluthatione
h	Hour(s)
HbsAg	Hepatitis B Surface Antigen
HDPE	High Density Polyethylene
HIV	human immunodeficiency virus
HO-1	Heme Oxygenase-1
HPLC	High Performance Liquid Chromatography
HPMC	Hydroxypropyl-methylcellulose
HR	Hazard Ratio
i.m	Intramuscular
i.p	Intraperitoneal
i.v. or IV	Intravenous
ICH	International Conference on Harmonisation
ILN	Lymph node
INEC	Independent Neurology Evaluation Committee
IR	Infra-Red Spectroscopy
ITT	Intention To Treat
IVRS	centralised interactive voice response system
Kim-1	Kidney Injury Molecule 1
LC/MS	Liquid Chromatography/Mass Spectrometry

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